

## Welcome to the Integrated Research Application System

## IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

**Please enter a short title for this project** (maximum 70 characters)  
HORIZONS: Understanding the impact of cancer diagnosis and treatment

**1. Is your project research?**

Yes  No

**2. Select one category from the list below:**

- Clinical trial of an investigational medicinal product
- Clinical investigation or other study of a medical device
- Combined trial of an investigational medicinal product and an investigational medical device
- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
- Basic science study involving procedures with human participants
- Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- Study involving qualitative methods only
- Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
- Study limited to working with data (specific project only)
- Research tissue bank
- Research database

**If your work does not fit any of these categories, select the option below:**

Other study

**2a. Please answer the following question(s):**

- a) Does the study involve the use of any ionising radiation?  Yes  No
- b) Will you be taking new human tissue samples (or other human biological samples)?  Yes  No
- c) Will you be using existing human tissue samples (or other human biological samples)?  Yes  No

**3. In which countries of the UK will the research sites be located?(Tick all that apply)**

- England
- Scotland

- Wales  
 Northern Ireland

**3a. In which country of the UK will the lead NHS R&D office be located:**

- England  
 Scotland  
 Wales  
 Northern Ireland  
 This study does not involve the NHS

**4. Which applications do you require?**

*IMPORTANT: If your project is taking place in the NHS and is led from England select 'IRAS Form'. If your project is led from Northern Ireland, Scotland or Wales select 'NHS/HSC Research and Development Offices' and/or relevant Research Ethics Committee applications, as appropriate.*

- IRAS Form  
 Confidentiality Advisory Group (CAG)  
 National Offender Management Service (NOMS) (Prisons & Probation)

*For NHS/HSC R&D Offices in Northern Ireland, Scotland and Wales the CI must create NHS/HSC Site Specific Information forms, for each site, in addition to the study wide forms, and transfer them to the PIs or local collaborators.*

*For participating NHS organisations in England different arrangements apply for the provision of site specific information. Refer to IRAS Help for more information.*

**Most research projects require review by a REC within the UK Health Departments' Research Ethics Service. Is your study exempt from REC review?**

- Yes  No

**5. Will any research sites in this study be NHS organisations?**

- Yes  No

**5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS Support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or a Diagnostic Evidence Co-operative in all study sites?**

Please see information button for further details.

- Yes  No

*Please see information button for further details.*

**5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?**

Please see information button for further details.

- Yes  No

*The NIHR Clinical Research Network provides researchers with the practical support they need to make clinical studies happen in the NHS e.g. by providing access to the people and facilities needed to carry out research "on the ground".*

*If you select yes to this question, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) immediately after completing this project filter question and before submitting other applications. Failing to complete the PAF ahead of other applications e.g. HRA Approval, may mean that you will be unable to access NIHR CRN Support for your study.*

**6. Do you plan to include any participants who are children?**

Yes  No

**7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?**

Yes  No

*Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.*

**8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?**

Yes  No

**9. Is the study or any part of it being undertaken as an educational project?**

Yes  No

**10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?**

Yes  No

**11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?**

Yes  No

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**Integrated Research Application System**  
**Application Form for Research administering questionnaires/interviews for quantitative analysis or mixed methodology study**


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**IRAS Form (project information)**

Please refer to the E-Submission and Checklist tabs for instructions on submitting this application.

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting [Help](#).

Please define any terms or acronyms that might not be familiar to lay reviewers of the application.

**Short title and version number:** (maximum 70 characters - this will be inserted as header on all forms)  
 HORIZONS: Understanding the impact of cancer diagnosis and treatment

Please complete these details after you have booked the REC application for review.

**REC Name:**  
 North West - Lancaster Research Ethics Committee

**REC Reference Number:**  
 16/NW/0425

**Submission date:**  
 12/05/2016

**PART A: Core study information**
**1. ADMINISTRATIVE DETAILS**
**A1. Full title of the research:**

HORIZONS: a cohort study to explore recovery of health and well-being in adults diagnosed with cancer

**A3-1. Chief Investigator:**

	Title	Forename/Initials	Surname
	Professor	Claire	Foster
Post	Professor of Psychosocial Oncology & Director of Macmillan Survivorship Research Group		
Qualifications	PhD, MSc, BSc, CPsychol		
Employer	University of Southampton		
Work Address	Faculty of Health Sciences, Building 67 Highfield Campus, University of Southampton University Road, Southampton		
Post Code	SO17 1BJ		
Work E-mail	C.L.Foster@soton.ac.uk		
* Personal E-mail	C.L.Foster@soton.ac.uk		
Work Telephone	02380 594006		

\* Personal Telephone/Mobile 07714138557

Fax

*\* This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*

*A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.*

**A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?**

*This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.*

	Title	Forename/Initials	Surname
	Miss	Becci	Petch
Address	Faculty of Health Science, Building 67, Room 2011		
	University of Southampton		
	Southampton		
Post Code	SO17 1BJ		
E-mail	horizons@soton.ac.uk		
Telephone	02380 598259		
Fax	02380 597951		

**A5-1. Research reference numbers. Please give any relevant references for your study:**

Applicant's/organisation's own reference number, e.g. R & D (if available):

Sponsor's/protocol number:

RHM CAN1199

Protocol Version:

1.0

Protocol Date:

05/05/2016

Funder's reference number:

Project website: [www.HORIZONS-HUB.ac.uk](http://www.HORIZONS-HUB.ac.uk)

**Additional reference number(s):**

Ref.Number	Description	Reference Number
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*Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.*

**A5-2. Is this application linked to a previous study or another current application?**

Yes     No

*Please give brief details and reference numbers.*

CREW (ColoRECTal Wellbeing) cohort: A longitudinal cohort study to explore recovery of health and well-being following primary treatment of colorectal cancer. Reference RHM CAN0737. UKCRN ID 9374. Funded by Macmillan Cancer Support.

**2. OVERVIEW OF THE RESEARCH**

*To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and*

*members of the public. Please read the guidance notes for advice on this section.*

**A6-1. Summary of the study.** *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

HORIZONS is a cohort study to explore recovery of health and well-being in adults diagnosed with cancer. Experiences and outcomes of cancer treatment and care are changing. A growing number of people are experiencing cancer not as a life-limiting disease, but as a life-changing and long-term condition. There is a growing imperative to understand the changing landscape of cancer and its consequences: as we do so, we will be better able to inform the design and delivery of cost effective interventions that make possible supported self-management, as well as service organization and delivery.

The key research questions are:

What impact does cancer and its treatment have on the lives of people diagnosed with cancer in the short, medium and long term?

What are the health outcomes, experiences and self-management activities over the life-course across different cancer types and who and what influence these?

HORIZONS is a series of prospective cohort studies of adults treated for non-metastatic cancer to capture their health outcomes and experiences from before they begin active treatment and regularly over their life-course. Our initial cancer cohorts will be breast cancer (diagnosed under age 50), non-Hodgkin lymphoma, and gynaecological cancers (ovarian, cervical, uterine). We will start recruitment with three pilot sites in NHS Trusts before rolling out full recruitment to approximately 50 NHS secondary care Trusts. Questionnaires will be completed before treatment (baseline), and followed up at regular intervals.

We will maintain and develop HORIZONS as a national and international resource to explore consequences of different cancer diagnoses and treatments from the individual perspective across the life-course.

**A6-2. Summary of main issues.** *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

*Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, HRA, or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.*

Purpose and design

The Macmillan HORIZONS Programme sets out to improve the lives of people affected by cancer by building understanding of the cancer survivorship population and providing a depth of evidence not available through other research. The purpose of this study is to invite all people diagnosed with cancer who meet the eligibility criteria to complete questionnaires before their treatment begins and at regular intervals over time to assess the impact of cancer and its treatment on people's lives in the short, medium and long term. We will explore a range of factors to determine their role in both recovery of health and wellbeing and self-management. Although it is known that people who have had cancer are likely to experience a number of physical and psychological problems as a result of the disease and treatment, it is not known what the 'typical' course of recovery of health and wellbeing looks like, how long it takes and how this can be influenced. We will determine pathways to recovery of health and wellbeing following cancer diagnosis and identify what factors influence this. This includes assessing the relative importance of the person's illness, personal attributes, perceived burden of treatment, role of the environment they live in, including health/social care and personal networks of support, and their ability and capacity to self-manage. We will identify who is most at risk of problems and what environmental supports and resources people are able to mobilise to support their self-management. We will also explore who has the confidence and ability to manage during and beyond treatment and what factors influence this and whether this leads to earlier problem resolution and restoration of health and well-being. This knowledge will be used to develop and test future supportive interventions to enhance the rapid recovery of health and well-being – our long term aim being to design ways of helping people with cancer in areas we identify as problematic for them.

The Southampton Macmillan Survivorship Research Group - directed by Prof Claire Foster aims to develop and deliver research that significantly contributes to the evidence base to improve the lives of people living with and beyond cancer. The CREW cohort of over 1000 colorectal cancer patients has been established to explore this (and is now in its 5th year of data collection). The research group has significant experience of cancer survivorship research and the methods used in the HORIZONS study have been extensively tested and refined based on our longstanding research programme (CREW (ColoREctal Wellbeing) cohort: (IRAS ID: 51866 REC Ref 10/H0605/31)).

The Director of the HORIZONS Programme has responsibility for delivery of the Programme. The Macmillan

Survivorship Research Group (MSRG) team is supported by Senior Academics, clinicians and patients who have contributed to developing the research proposal, which underwent peer-review as part of the funding application, and they will continue to advise and support the Programme according to their expertise in their roles as Co-applicants and Programme Associates. The MSRG research team has a long history of working closely with people affected by cancer (our Research Partners) to design, develop and deliver research programmes and projects. We are working closely with Research Partners in the design, development and delivery of the HORIZONS Programme alongside other stakeholders. The study has been peer reviewed externally by members of the relevant National Cancer Research Institute Clinical Studies Groups (Psychosocial, Gynaecological, Breast, NHL and Consumer Forum) and the funders Macmillan Cancer Support.

#### Recruitment

Within both the pilot phase and full study, eligible patients will be identified by a member of the patient's direct care team and research staff through multidisciplinary team meetings (MDT) or clinics at each participating site. It will be these site research staff who will approach patients about participation using the patient facing documents to support this approach.

#### Inclusion / exclusion

All eligible patients will be invited to participate in the assessment clinic after their cancer diagnosis and before their first primary treatment by a direct care team research nurse or member of the clinical team. Care must be taken to ensure all patients are approached, to ensure all groups are equally represented, in order that the research is able to make accurate observations of who is at risk and may need more support. Care should also be taken to ensure that patients from ethnic minorities and oldest age groups are also approached to participate so there is no selection within the eligible patient group by the clinician.

Participation in other research studies is not an exclusion criteria for this study, the HORIZONS Coordinating Centre will encourage and support site staff to give information to all eligible participants to allow them to choose if they want to participate in the study. If the patient is participating in, or considering participation in another study, HORIZONS should still be offered to the patient, unless it is an exclusion criterion of another study to which the participant is already consented.

#### Consent

Following the provision of the patient information sheet the clinical team's research staff will discuss with the patient if they wish to participate in the study. If the patient is interested in participating they will be given an opportunity to ask any questions before being given the Consent Form and being asked to provide fully informed written consent. Staff taking consent will be network funded cancer research nurses experienced in seeking consent from cancer patients or members of the clinical team. We will ensure that the members of the local site team named on the delegation log to seek consent have up to date GCP and have training (if required) to seek consent and assess capacity. This will be incorporated into site initiation visits or events.

If a patient feels that they would prefer not to complete questionnaires but would like to support the research they can provide reduced consent for the researchers to have access to their medical records, through the site research team's completion of CRFs. This option will be discussed by the site research team with the patient along with the option to decline to participate in the research so the patient can make an informed decision of all options.

#### Risks, burdens and benefits

People who are newly diagnosed with cancer and preparing for primary treatment are likely to be at a vulnerable time in their lives and the researchers appreciate this is a difficult time to approach a patient about participating in a clinical research project. The research team has significant experience of working with people who have cancer and their carers and have taken this into account in the design of the study. Patients will only be approached by an agreed member of their local clinical team. This person will be a member of the direct care research team of this group of patients, so the patients will be familiar with them.

The patient information sheet will also make clear the potential risks and benefits associated with participating in the study. There is unlikely to be any direct personal benefit to participating nor do we anticipate that there will be any risks to participants. Patients will be advised prior to study entry that if they have any concerns about their health as a result of study participation, they should contact their doctor or nurse.

Contact with the Coordinating Centre will be via telephone, email or mail, based on the contact details provided by the participant. If the participant has queries about their treatment or need of further support the HORIZONS Coordinating Centre will refer them back to their GP or local specialist team.

Sometimes people find it difficult to talk or write about their experiences. We will be asking participant about their emotional health, for example, how they are coping. Participants will be advised that they do not have to answer questions in any questionnaire that they would prefer not to answer.

If patients feel they are finding any aspect of their experience particularly difficult the HORIZONS Coordinating Centre staff will also provide them with details of where they might get more support, such as Macmillan Cancer Support ([www.macmillan.org.uk](http://www.macmillan.org.uk)), and Maggie's Centres ([www.maggiescentres.org](http://www.maggiescentres.org)). Participants will be advised that they may also want to talk to their GP or hospital clinician if they have any more specific questions. Due to the anonymised nature of the completion of the questionnaire no individual response to questionnaire answers can be made by the Coordinating Centre, and participants will be made aware of this.

**Confidentiality**

All researchers at the Coordinating Centre and study site staff will comply with the requirements of the Data Protection Act 1998 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

The data will be handled in compliance with Good Clinical Practice guidelines and Data Protection laws, following procedures as laid out by the sponsor organisation (University Hospital Southampton NHS Foundation Trust). All data will remain confidential at all times.

We are aware that we are asking for patient identifiable data and that this poses a risk for confidentiality. The patient identifiable data will be supplied by the patient. The information from the medical records will not be identifiable. We will take strenuous steps to ensure confidentiality. The University of Southampton has strict regulations about confidentiality which conform to Caldicott Principles and we have taken further advice from our legal adviser for data protection and freedom of information.

**3. PURPOSE AND DESIGN OF THE RESEARCH****A7. Select the appropriate methodology description for this research. Please tick all that apply:**

- Case series/ case note review
- Case control
- Cohort observation
- Controlled trial without randomisation
- Cross-sectional study
- Database analysis
- Epidemiology
- Feasibility/ pilot study
- Laboratory study
- Metanalysis
- Qualitative research
- Questionnaire, interview or observation study
- Randomised controlled trial
- Other (please specify)

**A10. What is the principal research question/objective? Please put this in language comprehensible to a lay person.**

The key research questions are:

What impact does cancer and its treatment have on the lives of people diagnosed with cancer in the short, medium and long term?

What are the health outcomes, experiences and self-management activities over the life-course across different cancer types and who and what influence these?

**A11. What are the secondary research questions/objectives if applicable? Please put this in language comprehensible to a lay person.**

The Macmillan HORIZONS evidence will:

Improve understanding of the consequences of different cancers and treatments, impact of co-morbidities, impact of recurrence and late effects, characteristics that lead to increased risk of poor recovery, ability to self-manage and what helps or hinders this

Enable us to predict who is most likely to need support, what form this should take and when it should be available.

Help to prepare future patients for likely consequences and how long these might last following treatment so that they know what to look out for and when to seek support and to support decision making where appropriate

Support the transformation of care for people living with and beyond cancer. Better information, on short, medium and long term outcomes and experiences across cancer types and treatments, will enable health professionals to provide more personalized care to their patients tailored to their needs and to support people to live as healthy and active a life



as possible.

Inform the development of risk stratification models, such as likely proportion of patients in different follow-up pathways across cancer/treatment type

Identify areas for service innovation and other solutions to support cancer survivors and their personal networks to manage the consequences of cancer and its treatment across all aspects of their lives.

**A12. What is the scientific justification for the research? Please put this in language comprehensible to a lay person.**

Experiences and outcomes of cancer treatment and care are changing. A growing number of people are experiencing cancer not as a life-limiting disease, but as a life-changing and long-term condition. There is a growing imperative to understand the changing landscape of cancer and its consequences: as we do so, we will be better able to inform the design and delivery of cost effective interventions that make possible supported self-management, as well as service organization and delivery.

The number of people living with and beyond cancer in the UK is set to double, to an estimated 4 million, by 2030 [2]. Rising survival rates are due to improvements in detection and treatments with many people faring well after treatment. However, cancer and its treatment can have a considerable and long term impact on everyday life [3-5]. Most cancer diagnoses are in people over 65 years, and with an ageing population (around 23% of the UK population will be over 65 by 2035 [6]), and a stretched health care system there is growing concern about how best to support cancer survivors (people living with and beyond a cancer diagnosis). Healthcare services need to adapt to the rapidly growing number of people living with or beyond cancer.

Cancer survivors can face a range of challenges following primary treatment that can have a significant impact on all aspects of daily life [1]. Some consequences may resolve in the short term, others may persist for years or arise a long time after treatment [5]. These may require medical management and support as well as self-management. Some people will experience a recurrence following treatment for curative intent (the rate of recurrence varies considerably by cancer and treatment type) and undergo further treatment. Patients have highlighted the need for support in managing the impact of cancer on everyday life [3]. People can be unprepared for the impact cancer and its treatment can have on their lives, may feel vulnerable and experience loss of confidence and may struggle to access care and support [1,5,7,8]. This may have serious implications for recovery and the success of self-managed follow-up, and the amount of work survivors are able to undertake to gain timely access to appropriate services.

The National Cancer Survivorship Initiative [NCSI] document Living with and beyond cancer: Taking action to improve outcomes [9] describes the urgent need to better understand the survivorship population to identify unmet needs. Data are not routinely collected to determine numbers of people affected by particular consequences and how severely, or who is currently at risk of consequences. Existing studies, such as the national PROMS survey (cross-sectional survey of cancer survivors in England 1-5 years post diagnosis), demonstrate that many people experience problems, and are useful at highlighting key problems experienced, but often do not provide evidence that consequences of treatment can be directly attributed to the treatment [10,11]. Cross sectional surveys are also problematic in that those who are experiencing problems are most likely to respond and it is not possible to demonstrate that treatment causes problems or patterns of treatment burden over time (e.g. [12,13]). Prospective clinical trials are useful but are applicable only to a minority of patients and have high dropout rates [14]. Another problem is that quality of life assessments generally provide a narrow view of symptoms and psychological problems. Looking at quality of life alone does not give a full picture of the impact of consequences on everyday life, including the lives of those closest to the person diagnosed with cancer, or how they are managed.

HORIZONS aims to respond to the limitations of previously published work by establishing representative cohorts, with baseline assessment pre-treatment, and followed over time to understand the impact of cancer and its treatment over the life course.

1. Foster, C., Fenlon, D., 2011. Recovery and self-management support following primary cancer treatment. *British Journal of Cancer* 105 Suppl 1, S21-28.
2. Maddams, J., Utley, M., Moller, H., 2012. Projections of cancer prevalence in the United Kingdom, 2010-2040. *British Journal of Cancer* 107, 1195-1202.
3. Corner, J., Wright, D., Hopkinson, J., Gunaratnam, Y., McDonald, J.W., Foster, C., 2007. The research priorities of patients attending UK cancer treatment centres: findings from a modified nominal group study. *British Journal of Cancer* 96, 875-881.
4. Hewitt, M., Rowland, J.H., Yancik, R., 2003. Cancer survivors in the United States: age, health, and disability. *The Journals of Gerontology. Series A, Biological Sciences and Medical Sciences* 58, 82-91.
5. Foster, C., Wright, D., Hill, H., Hopkinson, J., Roffe, L., 2009. Psychosocial implications of living 5 years or more following a cancer diagnosis: a systematic review of the research evidence. *European Journal of Cancer Care (England)* 18, 223-247.
6. Office for National Statistics. *Population Ageing in the United Kingdom, its Constituent Countries and the European Union*, 2012.
7. Jefford, M., Karahalios, E., Pollard, A., Baravelli, C., Carey, M., Franklin, J., Aranda, S., Schofield, P., 2008. Survivorship issues following treatment completion--results from focus groups with Australian cancer survivors and health professionals. *Journal of Cancer Survivorship* 2, 20-32.

8. Hewitt, M.G., S. Stovall, E., 2005. From cancer patient to cancer survivor: lost in transition. National Academies Press, Washington DC.
9. Department of Health, Macmillan Cancer Support & NHS Improvement. Living with and beyond cancer: taking action to improve outcomes, UK 2013.
10. Armes, J., Crowe, M., Colbourne, L., Morgan, H., Murrells, T., Oakley, C., Palmer, N., Ream, E., Young, A., Richardson, A., 2009. Patients' supportive care needs beyond the end of cancer treatment: a prospective, longitudinal survey. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology* 27, 6172-6179.
11. Glaser, A.W., Fraser, L.K., Corner, J., Feltbower, R., Morris, E.J., Hartwell, G., Richards, M., Wagland, R., 2013. Patient-reported outcomes of cancer survivors in England 1-5 years after diagnosis: a cross-sectional survey. *BMJ Open* 3.
12. Breckons, M., Calman, L, Foster, CL., An online survey to examine cancer survivors' confidence to self-manage problems arising in the first 12 months following primary cancer treatment. *Macmillan Survivorship Research Group Report*, 2012.
13. Santin, O., Mills, M., Treanor, C., Donnelly, M., 2012. A comparative analysis of the health and well-being of cancer survivors to the general population. *Supportive Care in Cancer* 20, 2545-2552.
14. Bell, M.L., Kenward, M.G., Fairclough, D.L., Horton, N.J., 2013. Differential dropout and bias in randomised controlled trials: when it matters and when it may not. *British Medical Journal* 346, e8668.

**A13. Please summarise your design and methodology.** *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

Design: HORIZONS is a series of longitudinal cohort studies conducted in cancer survivors using mailed questionnaires to gather patient reported outcome measures to assess quality of life and well-being. The study design and methods are informed by on-going, cohort studies which aim to increase understanding of recovery and health and well-being among lung (Foster et al., 2014), colorectal (Fenlon et al., 2013) and breast cancer survivors (Fenlon et al., 2014).

We will apply for adoption to the Clinical Research Network portfolio. We will recruit patients from up to 50 cancer centres to cover a range of geographical locations, clinical settings and ethnically diverse populations. Initially we will start with three pilot sites.

For each cohort, we aim to recruit all newly diagnosed patients who will be treated with curative intent (based on clinical, cytological or histological diagnosis) for the included cancers cancer through their clinical teams prior to primary treatment. This proposal is for three cancer cohorts; breast cancer, under the age of 50 at diagnosis, gynaecological cancer or non-Hodgkin lymphoma.

To be included, patients must:

- Have a new diagnosis of one of the selected cancer types
- or
- Have new/second primary cancer at a site previously treated for cancer
- Have no distant metastases
- Be awaiting primary curative intent treatment (or soon after diagnosis for those not undergoing immediate treatment)
- Be ≥16 years old
- Be able to complete questionnaires in English
- Be able to provide written, informed consent

Patients will be excluded if:

- Disease is recurrence/progression (either locally advanced or metastatic) at an existing cancer site
- They are having treatment for a potentially curative recurrence of disease e.g. locally advanced disease (i.e. they have been previously treated for the same cancer)
- They have metastatic disease from a cancer at another site
- Previous diagnosis of cancer at any other site would not be grounds for exclusion unless disease was metastatic

Data collection methods: Data will be collected from medical records and using self-report questionnaires. The baseline questionnaire will be completed by participants at the point of cancer diagnosis, before primary curative intent treatment and then at 3 months, 9 months, 12 months, 15 months, 24 months and annually to five years post recruitment to assess the short, medium and long term outcomes and experiences across cancer types and treatments. On receipt of questionnaires these will be checked for completeness. Where more than 50% of questions on a page have been left blank, contact will be made by the coordinating centre to ask about and, if possible, complete missing items in order to reduce the amount of missing data. If a double page spread is left blank, we will contact the participant offering them the opportunity to complete the missing items. If the coordinating centre has not received the completed questionnaire back after three weeks, the researcher or a member of the local clinical team will attempt to contact the participant to see if they have received it and/or send a duplicate questionnaire.

We will also collect medical details data on disease and treatment directly from the clinical team through completion of case report forms. This is done for two reasons: 1. to reduce how much is asked in the questionnaires and thereby reduce participant burden; and 2. to increase the accuracy of the medical information collected.

**Measures:** Each questionnaire will include a number of validated measures informed by the model of recovery. Domains of assessment will include: health and well-being; pre-existing factors (e.g. socio-demographics), self-management of consequences and aftercare, and consequences of cancer diagnosis and treatment.

**Analysis:** Descriptive statistics will be used to characterise the primary outcome of quality of life and describe health status, well-being, and symptoms/functioning over time, as well as to summarise patients' self-management activities, and their capacity and confidence to self-manage problems. Longitudinal analyses will assess changes over time in these measures.

It is anticipated that descriptive reports will be produced for questionnaire data at each separate time-point, and that initial analyses and publications will focus on data from baseline up to two years of follow-up (as in our CREW cohort study), to capture short-term recovery. Longer-term outcomes up to five years will be analysed and written up separately.

**Sampling:** The sampling frame is all individuals meeting the eligibility criteria at the recruiting sites. All eligible individuals should be offered participation into the study, and all those providing consent will be enrolled.

**Sample size:** Sample size calculations are based on the primary outcome, which is a measure of quality of life. Taking into account 10% withdrawal, a range of 5-year survival rates according to cancer type, likely similarities between participants recruited from the same site, and rounding up to allow for subgroup analyses results in approximately 1000 participants per cohort. We estimate that around 3000 participants will be recruited for the 3 cohorts over 3 years (recruitment phase) from 50 sites.

**Timetable for study:** We propose an initial pilot phase of approximately three months to start in June 2016 in which the Coordinating Centre will work closely with the selected sites to refine and optimise study procedures. The study will then be rolled out to sites who have expressed interest in participating through the research network to approximated 50 cancer centres across the UK. These participating sites will recruit patients for three years to obtain the predicted sample size.

**A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?**

- Design of the research
- Management of the research
- Undertaking the research
- Analysis of results
- Dissemination of findings
- None of the above

*Give details of involvement, or if none please justify the absence of involvement.*

To date we have actively involved patients and service users in the development of the study protocol and the patient facing documents. This includes members of the NCRI Consumer Forum and 2 Research Partners (patient and public involvement representatives)

The study will incorporate guidance from members of the user community in a number of ways. Involvement of the public will benefit HORIZONS by enhancing the relevance and accessibility of the research. This will be achieved by working closely with a User Reference Group (URG) to develop more effective ways of working. For example, in the design, development and delivery of the HORIZONS alongside other stakeholders.

The URG will advise on all aspects of the programme such as the way participants are recruited, updated and contacted within HORIZONS. The group will also advise on study design, planning and contribute to, and review, study documentation and participant burden. We will invite our URG to attend events such as the programme launch, and they will be supported to contribute to the programme through means such Knowledge Cafe Event co-facilitation, data interpretation and paper writing.

We will hold Knowledge Café events in the community during the life of the study to bring together the public and people affected by cancer to support engagement and public understanding of HORIZONS. These events will be advertised using various media to ensure that we engage with the public across the UK. We will proactively seek engagement with those typically under-represented in research – e.g. older people, black and minority ethnic groups. The purpose of these events will be to critically examine and develop the research methods to broaden the reach of involvement in HORIZONS and contribute to the development of new grant applications. The study has been presented to the NCRI consumer reference group who will support the study providing advice/feedback as necessary.

#### 4. RISKS AND ETHICAL ISSUES

## RESEARCH PARTICIPANTS

**A15. What is the sample group or cohort to be studied in this research?**

Select all that apply:

- Blood
- Cancer
- Cardiovascular
- Congenital Disorders
- Dementias and Neurodegenerative Diseases
- Diabetes
- Ear
- Eye
- Generic Health Relevance
- Infection
- Inflammatory and Immune System
- Injuries and Accidents
- Mental Health
- Metabolic and Endocrine
- Musculoskeletal
- Neurological
- Oral and Gastrointestinal
- Paediatrics
- Renal and Urogenital
- Reproductive Health and Childbirth
- Respiratory
- Skin
- Stroke

Gender: Male and female participants

Lower age limit: 16 Years

Upper age limit: Years

**A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).**

To be included, patients must:

- Have a new diagnosis of one of the selected cancer types
- or
- Have new/second primary cancer at a site previously treated for cancer
- Have no distant metastases
- Be awaiting primary curative intent treatment (or soon after diagnosis for those not undergoing immediate treatment)
- Be  $\geq 16$  years old
- Be able to complete questionnaires in English (use of an interpreter may support reduced consent and allow collection of medical details)
- Be able to provide written, informed consent

Have the ability to complete questionnaires

**A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).**

Disease is recurrence/progression (either locally advanced or metastatic) at an existing cancer site  
 They are having treatment for a potentially curative recurrence of disease e.g. locally advanced disease (i.e. they have been previously treated for the same cancer)  
 They have metastatic disease from a cancer at another site (Previous diagnosis of cancer at any other site would not be grounds for exclusion unless disease was metastatic)

**RESEARCH PROCEDURES, RISKS AND BENEFITS**

**A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. These include seeking consent, interviews, non-clinical observations and use of questionnaires.**

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Consent	1	0	Approx 10-15 minutes	The study will be introduced to patients during their pre-treatment clinic visit. After the initial approach by the direct care team, the nurse/ research nurse will give patients outline information about the study in a participant information sheet and supporting information. If the patient is interested in taking part they will be provided with a consent form, contact details form, baseline questionnaire (with unique study ID) and a return post-paid addressed envelope. Participants will complete the consent form and contact details form with the local researcher who will return these to the HORIZONS Coordinating Centre by secure safe haven fax. The participant will complete the questionnaire in their own time and send to the Coordinating Centre using the pre-paid envelope.
Questionnaire	9	0	Approx 40 minutes	The patient will be given the baseline questionnaire by the local site researcher. The participant will take the questionnaire home to complete. The coordinating centre will mail follow up questionnaires with a cover letter to the participant's home address at 3 months, 9 months, 12 months, 15 months, 24 months, and then annually for the participant to complete at their own convenience and return in the pre-paid envelope. The questionnaire will include instructions for completion using a secure online portal, if preferred. If the coordinating centre has not received the completed questionnaire back after two weeks, the researcher will attempt to contact the participants to see if they have received it and/or send a duplicate questionnaire. Further funding will be sought at the end of our five year programme funding to continue follow up over the life course.

**A21. How long do you expect each participant to be in the study in total?**

We anticipate, subject to funding, we will include participants over their life course, completing annual questionnaires after the first two years. We have secured initial five year funding from Macmillan Cancer Support to establish the cohorts.

**A22. What are the potential risks and burdens for research participants and how will you minimise them?**

*For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes*

*to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.*

This study includes people who have had a recent diagnosis of cancer, who we wish to recruit prior to treatment. We recognise that this is a time when potential participants may be vulnerable, however it is important that we gain baseline information as close as possible to diagnosis so that we can assess health and wellbeing before treatment starts to evaluate their return to health.

We will work with members of the direct care team and local nurses /research nurses to recruit people to the study as they will know potential participants and whether they meet the eligibility criteria. They will also have the necessary training for communication with cancer patients and Good Clinical Practice training for recruiting patients to research studies.

We will inform patients (in the participant information sheet) about the study and about how they might access support if they are experiencing any particular worries or concerns related to their cancer. If somebody telephones for advice, or because they are concerned, we will also give them this information. This will include informing them about support leaflets available through Macmillan Cancer Support via their website or at local centres, which we will also offer to send them and suggesting they contact their GP and/or clinical team if they have any particular concerns.

Completion of the questionnaires may present a burden for some patients, particularly older people or those with poor eyesight. We have attempted to make the questionnaire as user friendly as possible to minimise this burden, and study documents and questionnaires have been reviewed by cancer patients. Further, we are offering participants the option to complete the questionnaire online, in line with the way many people complete information requests in their daily life. The option of online completion will also aid accessibility for participants who have special communication needs and have their own communication software installed on their computer. We will also be sensitive to the potential burden to participants when recruiting to the study. Evidence from the CREW study indicate that participants are willing to complete questionnaires pre-treatment and over time and this study has a 69% response rate at 4 year follow-up.

Some participants may feel some of the of the questions are of a sensitive nature, e.g. questions about changes in relationships, however the instructions for completing the questionnaire will stress that they do not have to answer anything they feel uncomfortable with and may just leave that question blank.

There is some potential risk of breach of confidentiality due to the collection of patient identifiable data. The participant provides the contact details by which they are willing to be contacted by the Coordinating Centre and transfer of this data from sites to the Coordinating Centre will be secure methods such as safe haven fax or by post. This is essential to the study and careful steps have been taken to reduce risk. All data will be anonymised prior to analysis and publication and no identifiable data will be publicly available.

It is unlikely that there will be any benefit to the individuals taking part in the study as the information will be used for the development of future interventions and the development of services. It is possible that the participants may benefit from these developments in the long term. Previous research experience suggests that people welcome the opportunity to share their experiences of diagnosis and treatment in order to enhance care for all.

There is also the possibility that writing down their experiences may encourage people to access help and support from health professionals that they may not otherwise have done. Our service user panel tell us that they welcome the opportunity to be involved in this kind of research.

The research team has significant experience of working with people who have cancer and their carers. Professor Claire Foster, Chief Investigator, has extensive research experience with people living with and beyond cancer. We have also taken advice from our user reference group and members of our study advisory committee, which includes clinicians and researchers who have undertaken cohort studies in cancer patients. Prof Foster will ensure that the research is carried out to the highest ethical standards at all times.

**A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?**

Yes  No

*If Yes, please give details of procedures in place to deal with these issues:*

The questionnaires may include some questions on topics that may be sensitive. Respondents will be asked to only answer those questions they feel comfortable answering. We understand that the study is of a sensitive nature, especially because it is approaching patients who are newly diagnosed with cancer. However, patients have demonstrated active interest in participating in studies which will support them in the various aspects of managing a cancer diagnosis.

Although questions are of a sensitive nature, the Macmillan Survivorship Research Group has considerable experience of working with this population, including the prospective CREW cohort on which HORIZONS is based. The CREW questionnaires have not caused upset to the participants. We therefore believe that this study is suitable for proportionate review.

**A24. What is the potential for benefit to research participants?**

Participants in the study are unlikely to gain any specific personal benefits. However, the research is likely to benefit future generations of people with cancer and participants may feel it is helpful and reassuring to be involved in this research.

**A26. What are the potential risks for the researchers themselves? (if any)**

Risks to the researchers are likely to be low. The main risk to the researcher relates to the sensitive nature of the subject area (cancer). The research team at Southampton University have access to research support supervision. Prof Foster and senior researchers will oversee the project, all have extensive experience in cancer research and in supporting researchers.

**RECRUITMENT AND INFORMED CONSENT**

*In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.*

**A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?** *For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

Potential participants will be identified by the designated person at the research site who will normally be the Principal or Co-Investigator, during MDT (multidisciplinary team) meetings and from screening clinic lists. A list of eligible people will be drawn up and all potential participants will initially be approached by a member of their direct care team and then a local nurse /research nurse will explain the study.

**A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?**

Yes  No

*Please give details below:*

The local Principal Investigator or Co-Investigator, who is part of the patient's existing clinical team, will attend MDT in order to identify eligible patients

**A27-3. Describe what measures will be taken to ensure there is no breach of any duty of confidentiality owed to patients, service users or any other person in the process of identifying potential participants.** *Indicate what steps have been or will be taken to inform patients and service users of the potential use of their records for this purpose. Describe the arrangements to ensure that the wishes of patients and service users regarding access to their records are respected. Please consult the guidance notes on this topic.*

Patient's records will be screened by members of the direct care team, who have access to these details in normal clinical care.

**A27-4. Will researchers or individuals other than the direct care team have access to identifiable personal information of any potential participants?**

Yes  No

**A27-5. Has prior consent been obtained or will it be obtained for access to identifiable personal information?** Yes  No

*If Yes, please give details below.*

Yes. The direct care/ local research team will introduce the study to the patient and explain what data would be passed on to the Coordinating Centre, if the patient chooses to participate and this is further explained in the patient information sheet. If the patient chooses to participate they will consent to passing this data on to the Coordinating Centre and complete a Contact Details Form, which will include details of their name and contact details, in order for the Coordinating Centre to send the participant questionnaires directly.

**A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?** Yes  No

*If Yes, please give details of how and where publicity will be conducted, and enclose copy of all advertising material (with version numbers and dates).*

A study information leaflet will be used in the waiting rooms of relevant clinics to raise awareness of the HORIZONS study; both for patients to be aware they may be invited to participate during their clinic appointment, and to empower patients to ask their about participation if they are eligible. Recruitment will not be directly from the leaflet.

**A29. How and by whom will potential participants first be approached?**

The study will first be introduced to potential participants by a member of their direct care team at a pre-treatment clinic visit. If the patient is willing to discuss the study, the local research nurse will explain the study in more detail and provide written information.

As an alternative to this process, an invitation to participate letter and Patient Information Sheet may be sent, in advance of their clinic appointment, to an eligible patient, along with their pre-appointment letter. They would then be approached at their clinic visit by a member of the direct care team and referred to the site research team who will discuss the study and give them the opportunity to ask any questions.

**A30-1. Will you obtain informed consent from or on behalf of research participants?** Yes  No

*If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.*

*If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.*

People who are eligible for the study will be invited to participate in the study by a local nurse /research nurse. This nurse or research nurse, as agreed by local arrangements, will explain the study in detail giving the patient a Participant Information Sheet, the opportunity to ask questions and the option to have more time to think about participation. If the patient would like to take part written consent will be taken by the local nurse/ research nurse.

*If you are not obtaining consent, please explain why not.*

*Please enclose a copy of the information sheet(s) and consent form(s).*

**A30-2. Will you record informed consent (or advice from consultees) in writing?** Yes  No**A31. How long will you allow potential participants to decide whether or not to take part?**



Potential participants are approached pre-treatment and the baseline questionnaire should be completed before the patient starts treatment.

If the patient's treatment regime allows patients may be approached in person by the local nurse/ research nurse and then re-approached to discuss consent at their next appointment prior to treatment, at least 24 hours later.

Alternatively, the patient information sheet may be sent to the patient with their appointment letter to consider the study prior to attending clinic and again this would allow at least 24 hours for consideration of participation.

However, there is also the option for the local nurse/ research nurse to approach patients about the study and consent them in the same appointment if the patient feels that they have had their questions answered and are confident they would like to participate.

Given the nature of this observational questionnaire study, it has been deemed by the NCRI consumer forum, in their review of this study, that taking consent at the point of approach is an appropriate option. Further, it reduces patient burden of having to attend another appointment to take consent especially at a time which is quite appointment intensive. This has worked well in other studies which the Macmillan Survivorship Research Group run which involves recruiting patients before their curative intent treatment: including colorectal cancer patients – CREW (ColoRECTal Wellbeing) cohort (IRAS ID: 51866 REC Ref 10/H0605/31) and lung cancer patients – Roy Castle Lung Cancer Cohort Feasibility Study (IRAS ID 120711, REC Ref 13/YH/0081); RCRT: recovery after lung cancer radiotherapy (IRAS ID: 179379 REC Ref: 15/YH/0254).

For any patients that feel they need more time to consider participation, but do not have another appointment prior to treatment, they will be given the patient information sheet, consent form, contact details form, baseline questionnaire and pre-paid envelope home to return directly to the coordinating centre if they would like to take part.

**A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?(e.g. translation, use of interpreters)**

Language Line facilities are available for those whose first language is not English, to understand the study sufficiently to give informed reduced consent to provide access to their medical records and completion of the demographic form.

The option of online completion will also aid accessibility for participants who have special communication needs for completion of the questionnaires and have their own communication software installed on their computer.

The questionnaires used in the full study are only validated in English and therefore full study participation is only available to those who can communicate sufficiently in English to complete questionnaires about their health and well-being.

**A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? Tick one option only.**

- The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- The participant would continue to be included in the study.
- Not applicable – informed consent will not be sought from any participants in this research.
- Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

*Further details:*

If we are made aware by the participant or their doctor that he/she is no longer able to consent to the study we will cease to mail questionnaires to him/her

*If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform participants about this when seeking their consent initially.*

**CONFIDENTIALITY**

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

#### Storage and use of personal data during the study

#### A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)? (Tick as appropriate)

- Access to medical records by those outside the direct healthcare team
- Access to social care records by those outside the direct social care team
- Electronic transfer by magnetic or optical media, email or computer networks
- Sharing of personal data with other organisations
- Export of personal data outside the EEA
- Use of personal addresses, postcodes, faxes, emails or telephone numbers
- Publication of direct quotations from respondents
- Publication of data that might allow identification of individuals
- Use of audio/visual recording devices
- Storage of personal data on any of the following:
  - Manual files (includes paper or film)
  - NHS computers
  - Social Care Service computers
  - Home or other personal computers
  - University computers
  - Private company computers
  - Laptop computers

#### Further details:

Principles that apply across these methods;

All patients will be allocated a study ID number which will be the one key identifier between different sets of data. Any identifiable data, such as names and addresses, will be stored with the study ID number and the participant consent forms in a locked cabinet accessible only by the study team. Names and addresses are required for follow up mailings of the study questionnaire, and GP details for notification of study participation to participant's GPs.

We require medical details which will be provided, identifiable only by the participant's study ID, by the local clinical teams who recruit the participants using a case report form. This is more accurate than obtaining data from the participants and reduces the burden on them. Sharing of confidential data between centres will be undertaken using safe haven fax or by post.

Electronic transfer; Participant status update checks will be asked of sites via email in which the participant is identified only by study ID

Participants will be given the option of completion of questionnaires online. Participants will only be identified by their study ID and will create a personal, password protected account. The completed questionnaires will be stored on a single password protected, encrypted electronic database stored on a secure server in a UK data centre (Slough, Berkshire). The physical security of the data centre has been assured. A signed SSL Certificate facilitates a secure connection between the website and the user, it also verifies the website's identity so that the user can be reassured that their sensitive information is safe. The user will see a 'padlock' symbol or a green 'https' in their browser, assuring them of the authenticity of the HORIZONS website.

Sharing of personal data with other organisations, use of personal addresses, postcodes, faxes, emails or telephone numbers; Participants provide their contact details to the Coordinating Centre for direct contact in relation to study procedures such as sending study questionnaires

Publication of direct quotations from respondents; No reference to identifiable personal data will be made in publication. Where qualitative results are provided any reference to identifiable data will be removed.

Use of audio/visual recording devices; Qualitative methods may use audio/ visual recording devices for transcription

Manual files;

Hard copy questionnaire data, identifiable only by the participant's study ID, will be kept in locked storage separate to any patient identifiable data. They will be transferred to and from the data entry company in person with no identifiable data attached.

All hard copies of the data are kept in locked cabinets accessible only by members of the immediate research team at the University of Southampton. The locked cabinets are kept in lockable offices of the Faculty of Health Sciences in the University of Southampton.

University computers, home or other personal computers; Demographic, medical and questionnaire response data will be stored on a networked university server system with individual staff login, on a shared access allocated drive, accessible only by members of the study team. This will be identifiable by a study number only. No identifiable data will be on the database and therefore no identifiable information will leave the University.

Access to this drive is regularly reviewed.

Participants contact details provided by the participant will be stored on a password protected database for use by the Coordinating Centre in sending questionnaires and correspondence directly to participants. This will be stored on a networked university server system with individual staff login, on a shared access allocated drive, accessible only by members of the study team. This will be separate to any research data

Questionnaire data, identifiable only by study ID, will be entered onto a database on computers belonging to the University of Southampton and stored on University of Southampton servers which are accessible only by password.

NHS staff will use the EDGE clinical research data management website to record recruitment details. No patient identifiable details will be transferred outside of each Trust, the Coordinating Centre will be provided with aggregate recruitment figures.

Access to medical records by those outside the direct healthcare team; The Coordinating Centre will conduct a proportionate system of site monitoring. In order for this to provide assurance of protocol and local policy compliance, data accuracy and verification access to selected medical records by the Coordinating Centre monitor of consented participants will be requested, facilitated by the site team.

**A37. Please describe the physical security arrangements for storage of personal data during the study?**

All hard copies of our data are kept in locked cabinets accessible only by members of the immediate research team at the University of Southampton in a code locked door in the Faculty of Health Sciences

**A38. How will you ensure the confidentiality of personal data? Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.**

The Coordinating Centre will only receive personal data from sites for patients who have consented to the study. Screening data on patients who were eligible but declined will be anonymous. Participant contact details (single hard copy) will be transferred by sites to the Coordinating Centre by secure means such as safe haven fax and kept securely locked in filing cabinets in the University of Southampton, Faculty of Health Sciences in locked offices which can only be accessed by a member of staff. Returned questionnaires will be locked in a secure filing cabinet and labelled with the study ID. A separate database will be maintained with patients' names and addresses for the purposes of mailing repeat questionnaires. No medical details or questionnaire data will be stored on this database. Both databases will be password protected.

The Chief Investigator will be the data guardian and will keep a copy of all study documents, patient consent forms and any patient identification lists for 10 years from the end of the study (The HRA define this as the end of collection of all data required to answer the research questions in the protocol). All electronic data will be stored on a secure, password-protected University of Southampton database server, accessible only to the research team. All data will be anonymised prior to leaving the Coordinating Centre premises for data processing and/or statistical analysis.

**A40. Who will have access to participants' personal data during the study? Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.**

The local clinical teams and research team members at the participating Trust in which the participant is recruited will have access to participants' personal data as part of their clinical care and their participation in the research study. Researchers at the University of Southampton will only have access to details which patients have consented to provide. At the Coordinating Centre (University of Southampton) the study team will have access to names and addresses of study participants, provided with the permission of the participant, in order to process repeat

questionnaires.

#### Storage and use of data after the end of the study

##### A41. Where will the data generated by the study be analysed and by whom?

Analysis of anonymised data will be undertaken by the researchers at University of Southampton under the supervision of Professor Peter Smith in Southampton Statistical Sciences Research Institute (S3RI) or other researchers employed by the Faculty of Health Sciences and working under the supervision of Professor Foster, accessible only through the secure University network and password protected system either at the University of Southampton or at the researcher's home. No identifiable material will be taken outside the University, including when questionnaires are sent to an external company for data entry.

##### A42. Who will have control of and act as the custodian for the data generated by the study?

	Title	Forename/Initials	Surname
	Professor	Claire	Foster
Post	Professor of Psychosocial Oncology & Director of Macmillan Survivorship Research Group		
Qualifications	PhD, MSc, BSc, CPsychol		
Work Address	Faculty of Health Sciences, Building 67 Highfield Campus, University of Southampton University Road, Southampton		
Post Code	SO17 1BJ		
Work Email	C.L.Foster@soton.ac.uk		
Work Telephone	02380 594006		
Fax			

##### A43. How long will personal data be stored or accessed after the study has ended?

- Less than 3 months  
 3 – 6 months  
 6 – 12 months  
 12 months – 3 years  
 Over 3 years

*If longer than 12 months, please justify:*

Personal data will be kept for over 3 years after the study has ended in order to notify participants of study results and contacting participants who have indicated they may be interested in taking part in future research.

##### A44. For how long will you store research data generated by the study?

Years: 10

Months:

##### A45. Please give details of the long term arrangements for storage of research data after the study has ended. Say where data will be stored, who will have access and the arrangements to ensure security.

Research data will be archived for 10 years using a secure archiving facility, approved by the Sponsor, accessible by the Coordinating Centre and Sponsor and regulatory authorities upon request.

**INCENTIVES AND PAYMENTS**

**A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?**

Yes  No

**A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?**

Yes  No

**A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?**

Yes  No

**NOTIFICATION OF OTHER PROFESSIONALS**

**A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?**

Yes  No

*If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.*

**A49-2. Will you seek permission from the research participants to inform their GP or other health/ care professional?**

Yes  No

*It should be made clear in the participant's information sheet if the GP/health professional will be informed.*

**PUBLICATION AND DISSEMINATION**

**A50. Will the research be registered on a public database?**

Yes  No

*Please give details, or justify if not registering the research.*

The study will be registered with the NIHR portfolio, the ISRCTN registry, clinicaltrials.gov and Cancer Research UK's registry. Further registrations may be made as we become aware of them

*Registration of research studies is encouraged wherever possible.*

*You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.*

**A51. How do you intend to report and disseminate the results of the study? Tick as appropriate:**

Peer reviewed scientific journals

- Internal report
- Conference presentation
- Publication on website
- Other publication
- Submission to regulatory authorities
- Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- No plans to report or disseminate the results
- Other (please specify)

Report to Macmillan Cancer Support(funding body). Macmillan Cancer Support may wish to utilise results of the study in its publications.

**A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?**

No reference to identifiable personal data will be made in publication. The majority of results from questionnaires will be quantitative. Where qualitative results (e.g. free text responses to open questions in the questionnaire) are provided any reference to identifiable data will be removed.

**A53. Will you inform participants of the results?**

- Yes  No

*Please give details of how you will inform participants or justify if not doing so.*

Research will be disseminated to research participants and other interested groups or communities. Feedback on the outcome of this research will be provided to participants through study newsletters which will provide links to our study group website where results will be posted in a format accessible to lay readers.

We will send updates about the study in newsletters by post or email to participants, and participants will be made aware of this in the participant information sheet.

We will make a summary of the findings available on the HORIZONS website ([www.HORIZONS-HUB.ac.uk](http://www.HORIZONS-HUB.ac.uk)) and send to participants who indicated in their consent form they would like to receive it.

**5. Scientific and Statistical Review**

**A54. How has the scientific quality of the research been assessed? Tick as appropriate:**

- Independent external review
- Review within a company
- Review within a multi-centre research group
- Review within the Chief Investigator's institution or host organisation
- Review within the research team
- Review by educational supervisor
- Other

*Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:*

An independent peer review of the HORIZONS programme was carried out, facilitated by the funder, Macmillan Cancer Support, in October 2013. The reviewers were external to the host institution and funder and not involved in the study in any way. Four national/international experts independently reviewed the proposal and comments were sent to the Chief Investigator for response. All reviewers agreed the Programme fundable following modifications. The CI responded, in collaboration with the co-applicants, to further successful peer review in November 2013.

The study has been presented and discussed at National Cancer Research Institute Psychosocial Oncology and Survivorship Clinical Studies Group (CSG, non-Hodgkin Lymphoma Subgroups and presentations are planned at the

Gynaecological and Breast CSGs. Nationally renowned experts who sit on our study committees have reviewed and commented the protocol.

*For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.*

*For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.*

**A56. How have the statistical aspects of the research been reviewed? Tick as appropriate:**

- Review by independent statistician commissioned by funder or sponsor
- Other review by independent statistician
- Review by company statistician
- Review by a statistician within the Chief Investigator's institution
- Review by a statistician within the research team or multi-centre group
- Review by educational supervisor
- Other review by individual with relevant statistical expertise
- No review necessary as only frequencies and associations will be assessed – details of statistical input not required

*In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.*

	Title	Forename/Initials	Surname
	Professor	Peter W.	Smith
Department	PhD, MSc, BSc		
Institution	University of Southampton		
Work Address	Social Statistics & Demography Social Sciences, University of Southampton Southampton		
Post Code	SO17 1BJ		
Telephone	02380 593191		
Fax			
Mobile			
E-mail	pws@soton.ac.uk		

*Please enclose a copy of any available comments or reports from a statistician.*

**A57. What is the primary outcome measure for the study?**

Quality of Life in Adult Cancer Survivors (QLACS) will be the primary outcome measure across cancer types and will be included at each time-point. QLACS was developed to assess QoL of adult cancer survivors. QLACS measures 12 domains of cancer survivorship; 7 generic domains (pain, fatigue, positive and negative feelings, cognitive and sexual problems, social avoidance) and five cancer-specific domains (financial problems, family distress, recurrence distress, appearance concerns, benefits from cancer). QLACS has been validated amongst cancer survivors (Avis, N.E., et al., Assessing quality of life in adult cancer survivors (QLACS). Qual Life Res, 2005. 14(4): p. 1007-23) and has good convergent validity with other QoL measures (e.g. FACT and SF36).

**A58. What are the secondary outcome measures?(if any)**

Areas under investigation will include:

- Pre-existing factors: including age, gender, social circumstances, co-morbidities.
- Cancer diagnosis and treatment (data collected on medical details form by sites).
- Consequences of cancer diagnosis and treatment: including physical symptoms, psychological problems, social

implications such as impact on social relationships and networks, practical implications (e.g. work-related problems, everyday chores, travel); perceived impact on everyday life including financial impact, and how this is experienced as burdensome to individuals.

- Self-management of consequences and aftercare: self-management activities.
- Personal factors: Individual characteristics such as reliance and confidence to self-manage; perceived burden of treatment; perceived support and resources that individuals have in order to manage consequences for themselves.
- Environmental factors: access to / utilisation of health and social care and other forms of support, including social support through family, friends, community, healthcare, social care, third sector and social networks
- Health and well-being: quality of life, health status, personal well-being.
- Life events.

**A59. What is the sample size for the research?** *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size: 3000

Total international sample size (including UK):

Total in European Economic Area:

*Further details:*

This proposal is for three cancer cohorts; breast cancer, under the age of 50 at diagnosis, gynaecological cancer or non-Hodgkin lymphoma. Each cohort sample size is 1,000 patients.

The sites listed within this regulatory application reflect the pilot phase in which three sites are participating. It is anticipated that recruitment will be rolled out to 50 UK cancer centres through a regulatory amendment. This sample size reflects the recruitment by the full study sites.

**A60. How was the sample size decided upon?** *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

Sample size calculations are based on the primary outcome measure (QLACS). The mean generic summary score for QLACS is 71.2 (SD 25.6)(Avis, N.E., et al., Assessing quality of life in adult cancer survivors (QLACS). *Qual Life Res*, 2005. 14(4): p. 1007-23). A difference of one half a standard deviation is often quoted as a minimum clinically important difference in sample size calculations: using 80% power to detect a difference of one half of a standard deviation at the 0.05 significance level would require 46 cases in the smaller of the groups and 103 in the larger of the groups to be compared, giving a total of 149; it is unlikely that equal-sized groups will arise in the analyses. Assuming an intra-cluster correlation of 0.05 to allow for similarities between participants from each site and an average of 50 participants per site the cluster correction increases this figure to 514 per cohort. Taking into account 10% withdrawal and a range of 5-year survival rates according to cancer type results in approximately 1000 participants required per cohort.

The sample size will be sufficient for other continuous measures, assuming the same size of difference (one half a standard deviation). Subgroup analyses within cohorts will be possible, but numbers will be small for some instances, limiting the conclusions that can be drawn from these.

**A61. Will participants be allocated to groups at random?**

Yes  No

**A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.**

For Theme 1: Recovery from cancer treatment

Descriptive statistics will be used to characterise the primary outcome of QLACS and describe health status (EQ-5D), well-being (PWI), and symptoms / functioning (EORTC) over time. Changes in these outcomes over time will be investigated using longitudinal methods including generalised estimating equations, and group-based trajectory analyses will investigate whether there are distinct subgroups of recovery within each cohort. Factors that may influence recovery will be included in the regression models, including cancer and treatment type, socio-demographics, treatment and symptom burden, social support, personal dispositions, self-efficacy, self-management, personal network support, lifestyle, comorbidities, utilisation of health and social services, and recurrence. The varying contribution of these factors will be assessed to determine which have the most influence on the outcomes of quality of life, health status, well-being and symptoms / functioning following treatment. Recurrence and survival (overall and



disease-specific) will be analysed using standard methods of survival analysis, such as Kaplan-Meier analysis. For Theme 2: Self-managing the consequences of cancer

Descriptive statistics will be used to summarise patients' self-management activities, and their capacity and confidence to self-manage problems, and longitudinal analyses as previously described will assess changes over time in the measures of self-management. Factors that may influence self-management will be investigated in the regression models, such as capacity to self-manage, social networks and community support, utilisation of health and social services, cancer recurrence and co-morbidities. Analyses will also explore how self-management relates to recovery of quality of life, health and well-being. Self-management activities will be compared across groups including cancer and treatment types using statistical methods already described, and analyses such as group-based trajectory analyses will investigate whether there are distinct subgroups with different follow-up care needs. Patterns of missing data will be investigated in the analysis.

Qualitative work is planned during the Programme and once details are known will be submitted as a protocol amendment. Patients will give consent to be approached about other related studies at initial consent and those who consent will be contacted to ask if they would like to participate in related qualitative studies. Full information will be given and additional consent to participate in these studies will be taken prior to any data collection. Quantitative data will be analysed using statistical packages such as SPSS and Stata.

## 6. MANAGEMENT OF THE RESEARCH

**A63. Other key investigators/collaborators.** *Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title	Forename/Initials	Surname
	Dr	Lynn	Calman
Post	Senior Research Fellow		
Qualifications			
Employer	Macmillan Survivorship Research Group		
Work Address	Faculty of Health Sciences University of Southampton Highfield, Southampton		
Post Code	SO17 1BJ		
Telephone	02380 598023		
Fax			
Mobile			
Work Email	l.calman@soton.ac.uk		

	Title	Forename/Initials	Surname
	Professor Dame	Jessica	Corner DBE
Post	Pro-Vice Chancellor (Rsearch & Knowledge Exchange)		
Qualifications			
Employer	The University of Nottingham		
Work Address	Executive Office - Trent Building University Park Nottingham		
Post Code	NG7 2RD		
Telephone	0115 82 32481		
Fax			
Mobile			
Work Email	jessica.corner@nottingham.ac.uk		

	Title	Forename/Initials	Surname
	Mrs	Joanne	Haviland

Post Principal Research Fellow  
 Qualifications  
 Employer Macmillan Survivorship Research Group  
 Work Address Faculty of Health Sciences  
 University of Southampton  
 Highfield, Southampton  
 Post Code SO17 1BJ  
 Telephone 02380 597860  
 Fax  
 Mobile  
 Work Email J.S.Haviland@soton.ac.uk

Title Forename/Initials Surname  
 Prof Carl May  
 Post Associate Dean of Research  
 Qualifications  
 Employer University of Southampton  
 Work Address Faculty of Health Sciences  
 Highfield,  
 Southampton,  
 Post Code SO17 1BJ  
 Telephone 0238059 8233  
 Fax  
 Mobile  
 Work Email c.r.may@soton.ac.uk

Title Forename/Initials Surname  
 Prof Alison Richardson  
 Post Clinical Professor in Cancer Nursing and End of Life Care  
 Qualifications  
 Employer University of Southampton  
 Work Address Faculty of Health Sciences  
 Highfield  
 Southampton  
 Post Code SO17 1BJ  
 Telephone 0238059 8233  
 Fax  
 Mobile  
 Work Email alison.richardson@soton.ac.uk

Title Forename/Initials Surname  
 Prof Anne Rogers  
 Post Professor of Health Implementation  
 Qualifications  
 Employer University of Southampton  
 Work Address Faculty of Health Sciences  
 Highfield  
 Southampton  
 Post Code SO17 1BJ  
 Telephone 023 8059 7912

Fax	
Mobile	
Work Email	A.E.Rogers@soton.ac.uk
	Title Forename/Initials Surname
	Professor Peter W. Smith
Post	Professor of Social Statistics, Director of the ESRC Administrative Data Research Centre for England, Deputy Director of Southampton Statistical Sciences Research Institute
Qualifications	PhD, MSc, BSc
Employer	University of Southampton
Work Address	Social Statistics & Demography Social Sciences, University of Southampton Southampton
Post Code	SO17 1BJ
Telephone	023 8059 4327
Fax	
Mobile	
Work Email	pws@soton.ac.uk

#### A64. Details of research sponsor(s)

##### A64-1. Sponsor

###### Lead Sponsor

Status:  NHS or HSC care organisation

Academic

Pharmaceutical industry

Medical device industry

Local Authority

Other social care provider (including voluntary sector or private organisation)

Other

*If Other, please specify:*

Commercial status: Non-Commercial

###### Contact person

Name of organisation University Hospital Southampton NHS Foundation Trust

Given name Sharon

Family name Davies-Dear

Address R&D Department

Town/city University Hospital Southampton NHS Foundation Trust, Level E, Laboratory & Pathology Block

Post code SO16 6YD

Country

Telephone 0238120 5078

Fax

E-mail sharon.davies-dear@uhs.nhs.uk

**Is the sponsor based outside the UK?** Yes  No

*Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.*

**A65. Has external funding for the research been secured?**

- Funding secured from one or more funders  
 External funding application to one or more funders in progress  
 No application for external funding will be made

What type of research project is this?

- Standalone project  
 Project that is part of a programme grant  
 Project that is part of a Centre grant  
 Project that is part of a fellowship/ personal award/ research training award  
 Other

Other – please state:

**Please give details of funding applications.**

Organisation Macmillan Cancer Support  
Address 89 Albert Embankment  
London  
Post Code SE1 7UQ  
Telephone 020 7840 7840  
Fax  
Mobile  
Email evidence@macmillan.org.uk

Funding Application Status:  Secured  In progress

Amount: £2,407,003.70

Duration

Years: 5

Months:

*If applicable, please specify the programme/ funding stream:*

What is the funding stream/ programme for this research project?

Macmillan Cancer Support: Macmillan Survivorship Research Group

**A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? Please give details of subcontractors if applicable.**

Yes  No

**A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?**

Yes  No

*Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.*

**A68-1. Give details of the lead NHS R&D contact for this research:**

	Title Forename/Initials Surname
	Mrs Sharon Davies-Dear
Organisation	University Hospital Southampton NHS Foundation Trust
Address	R&D Department
	University Hospital Southampton NHS Foundation Trust, Level E, Laboratory & Pathology Block
	SCBR - Mailpoint 138, Tremona Road, Southampton
Post Code	SO16 6YD
Work Email	sharon.davies-dear@uhs.nhs.uk
Telephone	0238120 5078
Fax	
Mobile	

*Details can be obtained from the NHS R&D Forum website: <http://www.rdforum.nhs.uk>*

**A68-2. Select Local Clinical Research Network for NHS Organisation identified in A68-1:**

Wessex

*For more information, please refer to the question specific guidance.*

**A69-1. How long do you expect the study to last in the UK?**

Planned start date: 01/01/2016

Planned end date: 31/12/2020

Total duration:

Years: 4 Months: 11 Days: 31

**A71-1. Is this study?**

Single centre  
 Multicentre

**A71-2. Where will the research take place? (Tick as appropriate)**

- England  
 Scotland  
 Wales  
 Northern Ireland  
 Other countries in European Economic Area

Total UK sites in study 3

**Does this trial involve countries outside the EU?**

- Yes  No

**A72. Which organisations in the UK will host the research? Please indicate the type of organisation by ticking the box and give approximate numbers if known:**

- |   |   |
|---|---|
| <input checked="" type="checkbox"/> NHS organisations in England                                  | 2 |
| <input type="checkbox"/> NHS organisations in Wales   |   |
| <input checked="" type="checkbox"/> NHS organisations in Scotland                                 | 1 |
| <input type="checkbox"/> HSC organisations in Northern Ireland                                    |   |
| <input type="checkbox"/> GP practices in England  |   |
| <input type="checkbox"/> GP practices in Wales  |   |
| <input type="checkbox"/> GP practices in Scotland   |   |
| <input type="checkbox"/> GP practices in Northern Ireland   |   |
| <input type="checkbox"/> Joint health and social care agencies (eg community mental health teams) |   |
| <input type="checkbox"/> Local authorities  |   |
| <input type="checkbox"/> Phase 1 trial units  |   |
| <input type="checkbox"/> Prison establishments  |   |
| <input type="checkbox"/> Probation areas  |   |
| <input type="checkbox"/> Independent (private or voluntary sector) organisations                  |   |
| <input type="checkbox"/> Educational establishments   |   |
| <input type="checkbox"/> Independent research units   |   |
| <input type="checkbox"/> Other (give details)   |   |

Total UK sites in study: 3

**A73-1. Will potential participants be identified through any organisations other than the research sites listed above?**

- Yes  No

**A74. What arrangements are in place for monitoring and auditing the conduct of the research?**

To ensure the principles, requirements and standards of good practice in the Research Governance Framework, against which this study are conducted, are adhered to the Coordinating Centre will conduct ongoing central data monitoring. To support this a pragmatic, proportionate system of site monitoring will be undertaken by the Coordinating centre which will give further assurance of protocol and local policy compliance, data accuracy and

verification.

#### A76. Insurance/ indemnity to meet potential legal liabilities

*Note: in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland*

**A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? Please tick box(es) as applicable.**

*Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.*

- NHS indemnity scheme will apply (NHS sponsors only)
- Other insurance or indemnity arrangements will apply (give details below)

NHS Indemnity will cover NHS staff Co-Investigators and Members of the Study Management team for the management of the research. University Staff will be covered by the University of Southampton's Professional Indemnity and Clinical Trials Insurance for the management of the research

*Please enclose a copy of relevant documents.*

**A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? Please tick box(es) as applicable.**

*Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.*

- NHS indemnity scheme will apply (protocol authors with NHS contracts only)
- Other insurance or indemnity arrangements will apply (give details below)

NHS Indemnity will cover NHS staff Co-Investigators and Members of the Study Management team for the design of the research. University Staff will be covered by the University of Southampton's Professional Indemnity and Clinical Trials Insurance for the design of the research.

*Please enclose a copy of relevant documents.*

**A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?**

*Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.*

- NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)
- Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

NHS Indemnity will cover NHS staff for the conduct of the research. University Staff will be covered by the University of Southampton's Professional Indemnity and Clinical Trials Insurance for the conduct of the research

*Please enclose a copy of relevant documents.*

**A78. Could the research lead to the development of a new product/process or the generation of intellectual property?**

Yes  No  Not sure

DRAFT



**PART C: Overview of research sites**

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.

Investigator identifier	Research site	Investigator Name
IN1	<input checked="" type="radio"/> NHS site <input type="radio"/> Non-NHS site	Forename: Nicola Middle name: Family name: Keay Email: nicola.keay@uhs.nhs.uk Qualification (MD...): BM MRCP Country: UNITED KINGDOM
	Country: England	
	Organisation name	SOUTHAMPTON UNIVERSITY HOSPITALS NHS TRUST
	Address	MAILPOINT 18 SOUTHAMPTON GENERAL HOSPITAL TREMONA ROAD SOUTHAMPTON HAMPSHIRE
	Post Code	SO16 6YD
IN2	<input checked="" type="radio"/> NHS site <input type="radio"/> Non-NHS site	Forename: Katharine Middle name: Family name: Lowndes Email: katharine.lowndes@hhft.nhs.uk Qualification (MD...): BSc, MB, BS, FRACP, FRCPath Country: UNITED KINGDOM
	Country: England	
	Organisation name	BASINGSTOKE AND NORTH HAMPSHIRE NHS FOUNDATION TRUST
	Address	ALDERMASTON ROAD  BASINGSTOKE HAMPSHIRE
	Post Code	RG24 9NA

IN3

- NHS site
- Non-NHS site

Country: Scotland

Institution name NHS Greater Glasgow and Clyde  
 Department name The Beatson West of Scotland Cancer Centre  
 Street address 1053 Great Western Road  
 Town/city Glasgow  
 Post Code G12 0YN

Forename Graeme  
 Middle name  
 Family name Lumsden  
 Email Graeme.Lumsden@ggc.scot.nhs.uk  
 Qualification (MD...)  
 Country UNITED KINGDOM

IN4

- NHS site
- Non-NHS site

Country: Northern Ireland

Institution name NHSCT  
 Department name Antrim Hospital  
 Street address Bush Road  
 Town/city Antrim  
 Post Code BT41 2RL

Forename Brendan  
 Middle name  
 Family name McFall  
 Email brendan.mcfall@northerntrust.hscni.net  
 Qualification (MD...)  
 Country UNITED KINGDOM

IN5

- NHS site
- Non-NHS site

Country: Scotland

Institution name NHS Ayrshire and Arran  
 Department name Ailsa Hospital Campus  
 Street address Dalmellington Road  
 Town/city Ayrshire  
 Post Code KA6 6AB

Forename Graeme  
 Middle name  
 Family name Lumsden  
 Email Graeme.Lumsden@ggc.scot.nhs.uk  
 Qualification (MD...)  
 Country UNITED KINGDOM

IN6

- NHS site
- Non-NHS site

Country: Wales

Forename Walid  
 Middle name  
 Family name Samra  
 Email walid.samra@wales.nhs.uk  
 Qualification (MD...)

IN7

Institution name Betsi Cadwaladr University Health Board  
 Department name Glan Clwyd Hospital  
 Street address Bodelwyddan  
 Town/city Denbighshire  
 Post Code LL18 5UJ

Country UNITED KINGDOM

NHS site  
 Non-NHS site

Country: Scotland

Forename Melanie  
 Middle name  
 Family name Tolson  
 Email melanie.tolson@borders.scot.nhs.uk  
 Qualification (MD...)  
 Country UNITED KINGDOM

IN8

Institution name NHS Borders  
 Department name Borders General Hospital  
 Street address Melrose  
 Town/city Roxburghshire  
 Post Code TD6 9BS

NHS site  
 Non-NHS site

Country: England

Forename Julie  
 Middle name  
 Family name Pascoe  
 Email julie.pascoe1@nhs.net  
 Qualification (MD...)  
 Country UNITED KINGDOM

IN9

Organisation name PLYMOUTH HOSPITALS NHS TRUST  
 Address DERRIFORD HOSPITAL  
 DERRIFORD ROAD  
 PLYMOUTH DEVON  
 Post Code PL6 8DH

NHS site  
 Non-NHS site

Country: England

Forename Natasha  
 Middle name  
 Family name Mithal  
 Email natasha.mithal@nhs.net  
 Qualification (MD...)  
 Country UNITED KINGDOM

Organisation name EAST KENT HOSPITALS UNIVERSITY NHS FOUNDATION TRUST  
 Address KENT & CANTERBURY HOSPITAL  
 ETHELBERT ROAD

IN10

CANTERBURY KENT  
Post Code CT1 3NG

- NHS site
- Non-NHS site

Country: England

Organisation name SURREY AND SUSSEX  
HEALTHCARE NHS TRUST  
Address EAST SURREY HOSPITAL  
CANADA AVENUE  
REDHILL SURREY  
Post Code RH1 5RH

Forename Samantha  
Middle name  
Family name Weller  
Email samantha.weller@sash.nhs.uk  
Qualification (MD...)  
Country UNITED KINGDOM

IN11

- NHS site
- Non-NHS site

Country: England

Organisation name EASTBOURNE DOWNS  
P/CARE CENTRE  
Address C/O EASTBOURNE  
DISTRICT  
GENERAL HOSPITAL  
KINGS DRIVE  
EASTBOURNE  
Post Code BN21 2UD

Forename Jo-Anne  
Middle name  
Family name Taylor  
Email jo-anne.taylor@nhs.net  
Qualification (MD...)  
Country UNITED KINGDOM

IN12

- NHS site
- Non-NHS site

Country: England

Organisation name GATESHEAD HEALTH NHS  
FOUNDATION TRUST  
Address QUEEN ELIZABETH  
HOSPITAL

Forename Karen  
Middle name  
Family name Roberts  
Email karen.roberts@ghnt.nhs.uk  
Qualification (MD...)  
Country UNITED KINGDOM

IN13

GATESHEAD TYNE AND WEAR  
Post Code NE9 6SX

- NHS site
- Non-NHS site

Country: England

Organisation name IPSWICH HOSPITAL NHS TRUST  
Address HEATH ROAD

Post Code IPSWICH SUFFOLK  
IP4 5PD

Forename Paul  
Middle name  
Family name Ridley  
Email paul.ridley@ipswichhospital.nhs.uk  
Qualification (MD...)  
Country UNITED KINGDOM

IN14

- NHS site
- Non-NHS site

Country: England

Organisation name LANCASHIRE TEACHING HOSPITALS NHS FOUNDATION TRUST  
Address CHIEF EXECUTIVE'S OFFICE

ROYAL PRESTON HOSPITAL  
SHAROE GREEN LANE,  
FULWOOD PRESTON  
LANCASHIRE  
Post Code PR2 9HT

Forename Pierre  
Middle name  
Family name Martin-Hirsche  
Email pierre.martin-hirsche@lthtr.nhs.uk  
Qualification (MD...)  
Country UNITED KINGDOM

IN15

- NHS site
- Non-NHS site

Country: England

Forename Amy  
Middle name  
Family name Humphries  
Email amyhumphries@nhs.net  
Qualification (MD...)

Organisation name	LEEDS TEACHING HOSPITALS NHS TRUST	Country	UNITED KINGDOM
Address	ST. JAMES'S UNIVERSITY HOSPITAL BECKETT STREET LEEDS WEST YORKSHIRE		
Post Code	LS9 7TF		

IN16

NHS site  
 Non-NHS site

Country: England

Forename	Barbara
Middle name	
Family name	Townley
Email	btownley@nhs.net
Qualification (MD...)	

Organisation name	EAST CHESHIRE NHS TRUST	Country	UNITED KINGDOM
Address	MACCLESFIELD DISTRICT GEN HOSPITAL VICTORIA ROAD MACCLESFIELD CHESHIRE		
Post Code	SK10 3BL		

IN17

NHS site  
 Non-NHS site

Country: England

Forename	Susannah
Middle name	
Family name	Alexander
Email	susannah.alexander@nnuh.nhs.uk
Qualification (MD...)	

Organisation name	NORFOLK AND NORWICH UNIVERSITY HOSPITALS NHS FOUNDATION TRUST	Country	UNITED KINGDOM
Address	COLNEY LANE COLNEY NORWICH NORFOLK		
Post Code	NR4 7UY		

IN18

NHS site  
 Non-NHS site

Forename	Karen
Middle name	
Family name	McAdam

Country: England

Email

karen.mcadam@pbh-tr.nhs.uk

Qualification  
(MD...)

Country

UNITED KINGDOM

Organisation name  
PETERBOROUGH AND  
STAMFORD HOSPITALS  
NHS FOUNDATION TRUST

Address  
EDITH CAVELL HOSPITAL  
BRETTON GATE  
BRETTON  
PETERBOROUGH  
CAMBRIDGESHIRE

Post Code  
PE3 9GZ

IN19

- NHS site
- Non-NHS site

Forename

Stephanie

Middle name

Family name

Ridgeway

Country: England

Email

stephanie.ridgway@tgh.nhs.uk

Qualification  
(MD...)

Country

UNITED KINGDOM

Organisation name  
TAMESIDE HOSPITAL NHS  
FOUNDATION TRUST

Address  
TAMESIDE GENERAL  
HOSPITAL  
FOUNTAIN STREET  
ASHTON-UNDER-LYNE  
LANCASHIRE

Post Code  
OL6 9RW

IN20

- NHS site
- Non-NHS site

Forename

Middle name

Family name

Country: England

Email

Qualification  
(MD...)

Country

Organisation  
name

Address

Post Code

**PART D: Declarations****D1. Declaration by Chief Investigator**

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.
4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.
5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.
6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.
7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.
9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:
  - ◊ Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
  - ◊ May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
  - ◊ May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
  - ◊ Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
  - ◊ May be sent by email to REC members.
10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.
11. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

**Contact point for publication** *(Not applicable for R&D Forms)*

*NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.*

Chief Investigator



- Sponsor
- Study co-ordinator
- Student
- Other – please give details
- None

**Access to application for training purposes** (*Not applicable for R&D Forms*)

*Optional – please tick as appropriate:*

I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Professor Claire Foster on 19/07/2016 09:24.

Job Title/Post: Director of MSRG and Professor of Psychological Oncology  
Organisation: University of Southampton, Faculty of Health Sciences  
Email: C.L.Foster@soton.ac.uk

DRAFT

**D2. Declaration by the sponsor's representative**

*If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64-1.*

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.
2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.
3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.
4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.
5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.
6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.

*Please note: The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*

7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.
8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by Mrs Sharon Davies-Dear on 19/07/2016 10:33.

Job Title/Post: Research Governance Officer  
Organisation: University Hospital Southampton NHS Foundation Trust  
Email: sharon.davies-dear@uhs.nhs.uk